Application/Control Number: 10/562,122 Page 2

Art Unit: 1626

DETAILED ACTION

1. Claims 4 and 18 are pending in the instant application.

Response to Amendment

2. The amendments to the claims filed on October 8, 2009 have been fully considered. The 35 USC 112 1st paragraph rejection has been obviated and is thus hereby withdrawn.

EXAMINER'S AMENDMENT

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Daniel Pereira on October 22, 2009.

The application has been amended as follows:

Cancel claim 3.

Claim 18. Line 1, replace "medicine containing" with "pharmaceutical composition comprising"; line 2, replace "and wherein the medicine" with "which".

Reasons for Allowance

4. The following is an examiner's statement of reasons for allowance: the claimed crystalline form of

Application/Control Number: 10/562,122 Page 3

Art Unit: 1626

Sodium trans-4-[1-[2,5-dichloro-4-[(1-methyl-1H-3-

indolylcarbonyl)amino)phenylacetyl]-(48)-methoxy(28)-

pymolidinylmethoxylcyclohexanecarboxylate pentahydrate

is novel and non-obvious over the prior art. The closest reference (eg. US 20070105935) neither anticipates nor makes obvious the instant invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusions

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUN JAE Y. LOEWE whose telephone number is (571)272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

Application/Control Number: 10/562,122 Page 4

Art Unit: 1626

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Golam M. M. Shameem/ Primary Examiner, Art Unit 1626

/Sun Jae Y. Loewe/ 10-22-2009